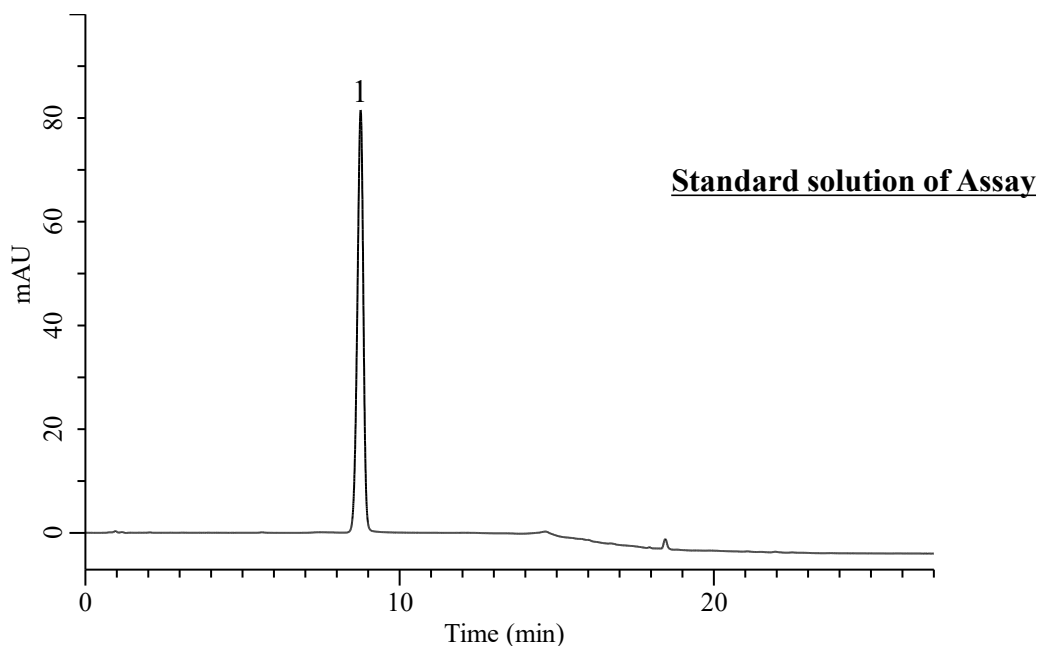


Analysis of Pregabalin

(Under the Condition of the draft for the Japanese Pharmacopoeia,
Pregabalin Orally Disintegrating Tablets)



Conditions

System : Chromaster PLUS HPLC system (HITACHI)1. Pregabalin
Column : InertSustain C18 (GL Sciences Inc.)
 (3.5 μ m, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-90600
Eluent : A) CH₃CN
 B) Solution*

Time(min)	A(%)	B(%)
0	1	99
10	1	99
15	25	75
27	25	75

Flow Rate : 1.0 mL/min
Col. Temp. : 25 °C
Detection : UV 210 nm
Injection Vol. : 50 μ L
Sample : Standard

Analyte:

1 mg/mL
 Tailing factor : 0.91 ($\leq$ 1.5)
 Number of theoretical plates : 9,720 ($\geq$ 3,500)
 RSD of the peak area (n=6) : 0.63 ($\leq$ 1.0)

* Dissolve 2.6 g potassium dihydrogen phosphate and 1.4 g dipotassium hydrogen phosphate in 1000 mL of water.